

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
7 April 2005 (07.04.2005)

PCT

(10) International Publication Number  
**WO 2005/031302 A2**

- (51) International Patent Classification<sup>7</sup>: **G01N** 21043-4143 (US). **HOAG, Stephen, W.** [US/US]; 205 Oak Forest Place, Baltimore, MD 21228-5624 (US).
- (21) International Application Number: **PCT/US2004/030977** (74) Agents: **VILLACORTA, Gilberto, M.** et al.; Katten Muchin Zavis Rosenman, 1025 Thomas Jefferson Street, NW, East Lobby, Suite 700, Washington, DC 20007-5201 (US).
- (22) International Filing Date: 22 September 2004 (22.09.2004) (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/504,774 22 September 2003 (22.09.2003) US (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LI, LU, PT, RO, SI, SK, TR, UA, UK, YU), Latin America and the Caribbean (AR, BO, BR, CL, CO, CR, CU, EC, EV, GR, GT, HN, IL, IN, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW).
- (71) Applicant (for all designated States except US): **UNIVERSITY OF MARYLAND, BALTIMORE** [US/US]; 520 West Lombard Street, Baltimore, MD 21201 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **POLLI, James, E.** [US/US]; 3524 Bucks County Court, Ellicott City, MD

[Continued on next page]

(54) Title: DRUG AUTHENTICATION

Table 1. Level 1 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 5%
Disintegrant	
starch	+/- 3%
other	+/- 1%
Binder	+/- 0.5%
Lubricant	
calcium or magnesium stearate	+/- 0.25%
other	+/- 1%
Glidant	
talc	+/- 1%
other	+/- 0.1%
Film coat	+/- 1%

Table 2. Level 2 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 10%
Disintegrant	
starch	+/- 6%
other	+/- 2%
Binder	+/- 1%
Lubricant	
calcium or magnesium stearate	+/- 0.5%
other	+/- 2%
Glidant	
talc	+/- 2%
other	+/- 0.2%
Film coat	+/- 2%

(57) Abstract: A method is disclosed to verify and identify pharmaceutical products through their product signatures in order to combat counterfeiting and reduce dispensing errors, using methods such as near infrared spectroscopy. Furthermore, in order actively evade pharmaceutical product counterfeiting, a method is disclosed where an amount of one or more of the inactive ingredients is varied over time; the variation provides a different product signature, but falling within a level deemed permissible by a regulatory body.

WO 2005/031302 A2



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

- *without international search report and to be republished upon receipt of that report*